CLAIMS

1. A method for determining the distribution of at least one outcome resulting from the administration of a compound to at least one human, comprising the steps of:

(a) using non-linear mixed effects modeling to determine a value and a standard error for each of a plurality of allometric parameters ;

(b) inputting said value and said standard error of at least one of said plurality of allometric parameters into a stochastic pharmacokinetic model, wherein said allometric parameter is designated as a random variable; and

(c) using said stochastic pharmacokinetic model to computationally simulate administration of said compound to said human to produce said distribution of said outcome.

2. The method according to claim 1, wherein at each of said allometric parameter is designated as a random variable with a specified probability density in said stochastic pharmacokinetic model.

3. The method according to claim 2, wherein said random variable has a mean value equal to the value of said allometric parameter, and a standard deviation equal to said standard error of said allometric parameter.

4. The method according to claim 3, wherein said specified probability density corresponds to either a normal distribution or a lognormal distribution.

5. The method according to claim 1, wherein said outcome is selected from AUC, Cmax, C24, Cavg, Cmin, or a pharmacodynamic response.

6. The method according to claim 5, wherein said pharmacokinetic response is selected from AUC, or Cmax.

7. The method according to claim 5, wherein said pharmacodynamic response is selected from inhibition or stimulation of a biological target.

8. The method according to claim 1, wherein said allometric parameter correspond to an allometically scaled pharmacokinetic parameter selected from clearance, volume distribution, or inter-compartmental volume.

9. The method according to claim 8, wherein said pharmacokinetic parameter is CL or V.

10. A method for selecting an optimal dose range of a compound for administration for the first time to a human, comprising the steps of:

(a) selecting one or more outcomes and distribution thereof derived according to the method of claim 1;

(b) based on said distribution selecting a minimum dose level corresponding to a desired level of safety or a desired minimum pharmacological effect; and

(c) based on said distribution selecting a maximum dose level corresponding to a desired level of safety and a desired maximal pharmacological effect.

11. An optimal dose range of a compound for administration for the first time to a human, wherein said optimal dose range is selected according to claim 10.